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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8
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Ref: 8EPR-SR

August 30, 1999

Dr. David Mellard
ATSDR
1600 Clifton Road (MS-32)
Atlanta, GA 30333

RE: Vasquez Boulevard/ Interstate 70 NPL Site,
Phase III Field Investigation

Dear Dr. Mellard:

Thank you for providing comments on behalf of ATSDR on the document, "Draft Project Plan for the Vasquez Boulevard & I-70 Site Phase III Field Investigation". Enclosed please find EPA's response to each of your comments.

Please note that in response to your comments #5 and #6, EPA requests a written proposal from ATSDR which addresses the scientific development of your recommended toxicity benchmark for arsenic soil exposure. Given the likely national implications of your recommendation, we wish to work with your agency to ensure a rigorous peer review of your proposal prior to proceeding with it at this site. We are currently seeking the advice of EPA Headquarters on the best course of action on this issue. We look forward to receiving the requested information to begin the peer review process.

If you have any questions about any of EPA's responses, please don't hesitate to call me at (303) 312-6579. Alternatively, our monthly working group meetings provide a forum to discuss your questions.

Sincerely,

Bonnie Lavelle
Remedial Project Manager

enclosure

cc: Susan Muza, ATSDR
VB/I-70 Working Group

Response to ATSDR Comments on the Phase III Workplan

Comment 1:

"The proposed sampling plan of collecting three composite samples from residential yards, parks, and schools does not protect children from harmful exposures to arsenic at the VBI70 site. The composite sampling plan may miss toxicologically significant "hot spots" of arsenic. In EPA's risk-based sampling report, location #10 show a property where most of the arsenic levels in the yard are very low while a few locations have high arsenic levels in soil. As shown in ATSDR's presentation to EPA's technical subgroup on June 10, 1999, children with high soil intake could have a one-time exposure to arsenic in soil that is at doses that could significantly harm their health."

Response 1:

EPA generally disagrees that the present sampling plan will miss toxicologically significant "hot spots". EPA , in cooperation with the VBI70 Workgroup, has designed a sampling program to assure that both adult and childhood health is protected for chronic, subchronic, and acute (hot spot) exposures. To assure that ATSDR concerns regarding the issue of hot spots were addressed in the Phase III sampling protocol, EPA significantly altered the plan following working group and technical subgroup discussions on this issue (June 10, 1999). Appendix D of the Phase III plan demonstrates the mathematical relationship between chronic and acute risk and how the sampling plan is designed to address issues raised by ATSDR to the workgroup. The Appendix D analysis demonstrates that protection of residents from unacceptable chronic (longer term) exposures will (in all biologically and statistically plausible cases) also protect residents, including children, from acute exposures. To assure full understanding of the proposed sampling design, EPA met with the technical subgroup on the afternoon of July 15, 1999 (including representatives from ATSDR) to discuss and fully explain the toxicological assumptions and mathematical analysis used to design the Phase III plan. It is EPA's understanding that the subgroup now unanimously agrees that the plan reasonably and scientifically addresses the issues raised by ATSDR in Comment #1. Appendix D reflects the discussions which occurred on July 15, 1999.

Comment #2:

"ATSDR recommends that EPA use the five subsections described in the sampling plan to define each composite sample. Therefore, the six grab samples from subsection one will be combined to form composite sample #1 and so on. Using each subsection as an individual composite provides a better chance of detecting "hot spots" of arsenic. Properties such as parks and school yards and very large residential properties may require more subsections."

Response #2:

EPA disagrees that using the subsections as individual composites will provide a more scientifically defensible method for detection of hot spots. The approach suggested in the comment will not provide a known level of statistical confidence in the measurement since only

one sample per exposure area would result. Such an approach is likely to produce an overestimation of mean[1] arsenic concentrations in each yard due to greater variance in the sample. EPA has designed the Phase III residential sampling plan to estimate the mean arsenic concentration and the variability in the arsenic concentration with reasonably high accuracy. In doing so, the sampling data collected following implementation of Phase III will allow reasonable and scientifically sound protection of residents from acute (short term) and subchronic (longer term) exposures in subareas as small as 10 feet by 10 feet and perhaps smaller. It is EPA's understanding that, following discussions and explanations provided by EPA to the technical subgroup of the VBI70 Working Group on July 15, 1999, that ATSDR now agrees that the Phase III plan is adequately protective under the scenarios discussed. EPA will be glad to further discuss the theory and practice of the Phase III sampling plan upon request.

Comment #3:

"In attachment 1 for acute exposures, ATSDR recommends using a soil intake level of 5,000 mg/day as a more realistic intake level for children with high soil intake (see Calabrese and Stanek, ELR News and Analysis, 28: 10660-10670, 1998.) EPA should note that Calabrese reports a case in his studies where a 2-year-old girl ingested 20 grams of soil per day."

Response #3:

EPA recognizes the phenomenon of abnormal ingestion of non-food items (technically termed 'pica behavior'). EPA also recognizes the importance of establishing practical and scientifically sound mechanisms to define risk for individuals displaying this behavior. The present plan described for the Phase III sampling is intended to allow risk assessors and project managers to identify individual homes where arsenic concentrations (average or "hot spots") range to a level of potential concern for children with abnormal soil ingestion behavior. However, as a matter of professional judgement and practical consideration, and following review of the Calabrese reanalyses of existing soil ingestion data, EPA may not be able to protect every child who may ingest up to 20 grams of soil in areas of extremely elevated arsenic. Such behavior may put children at risk of harm from substances outside of the present Superfund activity such as microbiological infection by various soil organisms, non-arsenical pesticides, and lead-based paint exposure . However, it should be noted that the likelihood of a child who displays pica behavior encountering an area of elevated arsenic at the precise time of the behavior is extremely low.

Comment #4:

"In attachment t 1 for acute exposures, ATSDR recommends using 10 kg body weight rather than the average weight of a child aged one to six. The reason for this change is that a one to two year old child is at greater risk because of their lower body weight."

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[1] In order to avoid underestimation of the mean arsenic concentration (and resulting underestimation of risk) EPA uses the 95% upper confidence level of the mean (95% UCL) to estimate possible exposures. This calculation is made using at least three independent sample analyses collected from the same distribution.

Response #4:

EPA national default exposure parameters for assessment of chronic risk includes a recommendation for using a 15 kg body weight for children. However, the ATSDR recommendation to use 10 kg for screening short term risk is consistent with the EPA use of this parameter for the removal action at the site. EPA accepts the recommendation and will incorporate this parameter in the screening procedure for acute risk evaluation.

Comment #5:

"In attachment 1 for acute exposures, EPA is using an outdated acute Minimal Risk Level (MRL). ATSDR's 1999 draft Toxicological Profile for Arsenic does not cite an acute oral MRL for arsenic. In ATSDR's presentation to EPA's technical working group for the VBI70 site on June 10, 1999, ATSDR presented several papers showing that harmful effects could occur in humans exposed one time to 0.06 mg of solubilized As/kg/day."

Response #5:

Neither EPA nor ATSDR presently have toxicological benchmarks (Reference Doses or Minimal Risk Levels (MRLs)) for acute (short term) high intensity exposures to arsenic. However, as eluded to in the ATSDR comment, toxicological information to develop such benchmarks may currently be available in the open literature. ATSDR recommends the use of an acute MRL of 0.06 mg/kg-day as applicable for short term exposures to arsenic. To support this MRL, ATSDR proposes to use data presented in Mizuta et al., 1956 and Franzblau and Lilis, 1989. Both of these studies present data on short term exposure to arsenic which, according to the ATSDR interpretation, resulted in toxicologically significant effects (LOAEL). Both studies report exposures to individuals who may not represent the toxicologically most sensitive subpopulation (such as children, the elderly, or the infirmed). Typically, when EPA sets toxicological benchmarks, an added uncertainty factor of 10 is used to assure that sensitive individuals are protected and an additional factor of 10 added to extrapolate from the LOAEL to the NOAEL. Using this more conventional approach to establishing an acute benchmark for arsenic exposure coupled with the proposed effect level of 0.06 mg/kg-day proposed by ATSDR, the resulting MRL might be as low as 0.006 mg/kg-day or lower. This proposed acute benchmark is considerably lower than the previously recommended value and is unusually close to the value employed by ATSDR or EPA to protect for chronic exposures.

Given the precedential proposal by ATSDR to employ this low and previously unused toxicity benchmark for arsenic soil exposure, EPA requests a written proposal from ATSDR addressing the scientific development of the MRL. The proposal will be most useful if it includes; 1) justification for the choice of principle studies, 2) explanation of the dose estimates made, 3) a designation of the NOAEL or LOAEL, and 4) discussion of the application and rationale for uncertainty factors chosen. Given the likely national implications of establishing an acute MRL for arsenic at the proposed level, we also recommend consideration of more rigorous peer review prior to proceeding.

Comment #6:

"At the acute RBC of 7,500 mg/kg arsenic proposed in Appendix 1, the estimated dose for children with a one-time exposure at 7,500 mg/kg is to 3 mg/kg/day. That dose has caused severe gastrointestinal effects and neurological effects (Mizuta et al., 1956; Franblau and Lilis, 1989)(see ATSDR's 1999 Toxicological Profile for citations.) That dose is so dangerously close to levels that could cause hemorrhagic bronchitis, gastrointestinal bleeding, acute renal failure, encephalopathy, and peripheral neuropathy. ATSDR strongly recommends that EPA withdraw this RBC. Note: Table 2-3 in the toxicological profile reports exposure periods of two to three weeks in the Mizuta paper and one to two months in the Franzblau paper. A closer read of the papers shows that harmful effects occurred within 24 hours of exposure, making the papers appropriate to use to evaluate a one-time exposure in children. Also, the dose in the Franzblau paper is incorrectly reported in the profile. The actual dose is 0.06 mg/kg/day."

Response #6:

RBCs are set using both exposure assumptions and toxicity benchmark values. **Toxicity benchmarks** are broadly applicable to sites throughout the nation while **exposure assumptions** are specific to each site. The Phase III sampling plan is intended to provide a detailed plan for collection of data to support a site-specific exposure assessment at the VBI70 site. It will include the collection of residential soils and housedust. The soil samples collected will also be used in a future site specific measurement of arsenic absorption or bioavailability. The collection of this data has been designed around protection of human health using nationally acceptable toxicity benchmarks. That is to say that the number of samples collected and the manner in which they are analyzed is designed to assure protection under both acute (short term) and chronic (longer term) exposure conditions.

EPA will fully consider recommendations for new toxicity benchmarks if they are scientifically sound and submitted with appropriate background information (see response to comment #5). EPA recommends appropriate and thorough review of any proposed toxicity benchmarks which have the potential to set national precedent.

Comment #7:

"Children with high soil intakes are likely to do so several times in a short period (see Calabrese's ELR paper). It's reasonable to assume that a child could have high soil intake (5,000 mg/kg/day) three times in one week, which gives a dose of 1.6 mg/g/day. That dose is close to the 2 mg/kg/day dose that has caused peripheral neuropathy and death in humans (Armstrong et al, 1984)."

Response #7:

EPA agrees that pica behavior can and does occur in children and that a reasonable measure of protection against adverse exposures should be attained if possible. However, it is important to note that Dr. Calabrese's report is based upon modeled (not measured) estimates of pica behavior frequency. Actual pica frequency data for the population is not presently available. It is important to also remember that the likelihood of pica behavior occurring in an area of elevated arsenic contamination is low.

Assuming the ingestion mass (5 grams) and frequency (3 days/week) presented in the comment is plausible, the comment is incomplete as estimates of soil arsenic concentrations and body weight are missing.

Comment #8:

"ATSDR recommends that since GFAA or ICP/MS is being used for indoor dust samples that the same analytical methods be used for the corresponding outdoor soil samples. Using the same analytical method will allow a better comparison between outdoor soil levels and indoor dust levels."

Response #8:

EPA agrees that a quality assured and controlled comparison between analytical techniques used on the site is essential. The choice of analytical method for the various media being studied as part of Phase III is based on the required project detection limits which are established to achieve the stated project objectives.